

## REMARKS

This Amendment and Response is submitted in response to the Office Action mailed August 19, 2004. Claims 2-3, 5-9, 24-26, and 28-41 are pending after entry of this amendment. Withdrawal of the rejection and reconsideration with an eye toward allowance is respectfully requested.

### **Claim Rejections – 35 U.S.C. §112**

Claims 2-3, 5-9, 24-34 and 36-41 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. First, the Examiner asserts that the term “biochip cartridge” is not sufficiently described in the claims. Second, the Examiner asserts that “said outlet port” in Claim 26 lacks proper antecedent basis in the claims. Third, the Examiner asserts that the recitation “to minimize the introduction or retention of air bubbles upon introduction of reagents” does not limit or define a physical relationship between the inlet and outlet ports. Fourth, the Examiner asserts that Claim 25 lacks proper antecedent basis in Claim 24 for its recitation of “said outlet port.” Fifth, the Examiner asserts that Claim 27 is indefinite for the recitation “preferentially allows the escape of gas and retains fluid” because it is unclear what structural limitations are being imposed on the membrane. Finally, the Examiner asserts that Claim 38 is indefinite for the recitation “an assay complex is formed on at least one of said electrodes” because it is unclear whether the recitation limits the structures or components of the cartridge.

Applicants respectfully submit that, in light the amendments presented above (under the heading “Amendments to the Claims”) the pending claims are sufficiently definite and withdrawal of the rejections under 35 U.S.C. § 112 is requested.

### **Claim Rejections – 35 U.S.C. §102**

Claims 24, 2, 5, 7-8, 31 and 36-41 stand rejected as anticipated by Lennox et al., US Patent No. 6,461,490 (“Lennox”). Lennox teaches a method of detecting target analytes wherein a capture probe is immobilized on an electrode via the non-covalent

hydrogen bonding of two peptides (one attached to the capture probe and the other attached to the electrode) that together form an alpha-helical coiled coil.

For an anticipation rejection under 35 U.S.C. §102 to be proper, a single reference must expressly or inherently disclose each and every element of a claim. In *re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); MPEP § 2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Each of the instant claims recite capture binding ligands covalently attached to an electrode. As discussed above, *Lennox* does not teach a system employing covalently attached capture binding ligands. Accordingly, the Examiner has not carried her burden under §102, and Applicants respectfully request withdrawal of the rejection.

Claims 24, 2-3, 5, 7-8, 31, 36-37 and 39-40 stand rejected as anticipated by *Ribi et al.*, US Patent No. 5,491,097 ("Ribi"). *Ribi* teaches a bioelectronic sensor comprising (1) an electrically insulating solid support or substrate, (2) a highly oriented polymerized surfactant film which is electrically semiconducting or variably conducting as a result of the polymerization, and (3) distal from the support, a member of a specific binding pair joined to the surfactant molecules, wherein the specific binding pair member is used for linking to a molecule. The binding of a target to the binding member results in a change in the electromagnetic properties of the surfactant film, creating a detectable signal at the electrodes positioned on the substrate to either side of the film. See column 3, lines 17-24. Each test requires two electrodes, as it is the change in the electromagnetic properties of the surfactant film between these two electrodes that produces the detection signal. Accordingly, *Ribi* does not teach capture binding ligands covalently attached to electrodes.

As pointed out above, an anticipation rejection under 35 U.S.C. §102 to be proper, a single reference must expressly or inherently disclose each and every element of a claim. In *re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); MPEP § 2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Again, each of the instant claims recites capture binding ligands covalently attached to an electrode. As discussed above, *Ribi* does not teach a system employing covalently

attached capture binding ligands. Accordingly, the Examiner has not carried her burden under §102, and Applicants respectfully request withdrawal of the rejection.

### **Claim Rejections – 35 U.S.C. §103**

Claims 6, 2-3, 5, 7-9, 24-33, and 36-41 stand rejected as unpatentable over Lennox in view of Anderson et al., US Patent No. 6,326,211 (“Anderson”). As discussed above, Lennox teaches a system that relies on non-covalent attachment of capture binding ligands to peptides attached to electrodes. Anderson teaches cartridge components that can be used in connection with target analyte systems, but does not disclose individual detection systems.

To establish a prima facie case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. See, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) M.P.E.P. §2143.

As discussed above, the system described in Lennox relies on the non-covalent hydrogen bonding of two peptides to form an alpha-helical coiled coil to immobilize capture probes to an electrode. Accordingly, Lennox does not teach or suggest the use of capture binding ligands covalently attached to electrodes. Anderson does not cure this deficiency, as Anderson only teaches various cartridge architectures and does not teach specific methods of target analyte detection. As the cited art does not teach or suggest all of the claim limitations, the Examiner has not established a prima facie case of obviousness and withdrawal of the instant rejection is respectfully requested.

Claim 34 stands rejected as unpatentable over Lennox, Anderson and further in view of Hayes et al, US Patent No. 6,326,211 (“Hayes”). Lennox and Anderson are described above. Hayes teaches a miniature apparatus for performing biochemical reactions with a removable top. Hayes does not teach specific target analyte detection methods.

As discussed above, to establish a prima facie case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim


limitations. See, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) M.P.E.P. §2143.

As was discussed above, the system described in Lennox relies on the non-covalent hydrogen bonding of two peptides to form an alpha-helical coiled coil to immobilize capture probes to an electrode. Accordingly, Lennox does not teach or suggest the use of capture binding ligands covalently attached to electrodes. Neither Anderson nor Hayes cure this deficiency, as Anderson and Hayes only teach various cartridge architectures and do not teach specific methods of target analyte detection. As the cited art does not teach or suggest all of the claim limitations, the Examiner has not established a prima facie case of obviousness and withdrawal of the instant rejection is respectfully requested.

## CONCLUSION

Applicants submit the claims are in condition for allowance, and notification of such is respectfully requested. If after review, the Examiner feels there are further unresolved issues, the Examiner is invited to call the undersigned at (415) 781-1989.

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